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The First Year Experience with the Dual Chamber ICD

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HIGGINS, S.L., ET AL.: **The First-Year Experience with the Dual Chamber ICD.** *In July 1997, a dual chamber pacemaker combined with a tiered therapy implantable cardioverter defibrillator (ICD) first became available in the United States. We report the first-year experience of one center in the United States with this dual chamber ICD. Of a total of 174 ICDs, 95 (55%) were dual chamber devices and 79 (45%) were single chamber. New dual chamber ICD insertions averaged 57.4 ± 8.9 minutes, though there was a learning curve as the last 30 implants averaged 45.1 ± 6.1 minutes with a negative slope to the regression line of procedure duration (−0.52, $P < 0.05$). New single chamber ICD implants were 18.5 minutes quicker (38.9 ± 7.2 minutes). The most challenging implants were dual chamber upgrades (mean procedure duration 64.9 ± 15.8 minutes), especially if there was a previously implanted pacemaker and ICD at separate sites. Indications for a new dual chamber device were grouped into classic pacemaker indications (52.5%), which comprised the Class I ACC/AHA guidelines, ICD-specific indications (24.6%), and other (23.0%). In the 34 patients undergoing dual chamber upgrade, the classic and ICD-specific groups were equal (47.0% each). Complications were rare (2.8%), though 3 (8.8%) of 34 undergoing a dual chamber upgrade developed late infections requiring explantation. In its first year, the dual chamber ICD has become a common device at our institution comprising 55% of new implants. As experience grows, we anticipate similar usage at most institutions. (PACE 2000; 23:18–25)*

implantable cardioverter defibrillator, dual chamber pacing, permanent pacemakers, ventricular fibrillation, ventricular tachycardia, sudden death

Introduction

Since 1990, single chamber bradycardia pacing has been an available feature in the implantable cardioverter defibrillator (ICD). However, until recently, patients who required dual chamber pacing and an ICD received two separate generator and lead systems with an associated risk of device-device interactions.[1–3] In July 1997, a dual chamber pacemaker became available in the United States combined with a tiered therapy ICD (hereafter referred to as "dual chamber ICD," meaning dual chamber pacing with single chamber [ventricular] defibrillation). Although the dual chamber device requires an additional lead compared to the single chamber ICD, it is still less complicated than the separate introduction of a pacemaker with an ICD that requires three leads.

Published prerelease estimates regarding anticipated usage of the new dual chamber ICD varied anywhere from 5% to 55% of implants in the United States.[4,5] We report a single center's first year of experience with this new technology including new dual chamber ICD implantations, upgrades from a single chamber ICD to a dual chamber device, and generator changes to a dual chamber ICD whether or not a separate pacemaker was previously present. The dual chamber recipients are compared to a concurrent control group who received a single chamber ICD.

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Methods

Patient Population

Prospectively, data was obtained for all ICD implantations and generator changes performed at Scripps Memorial Hospital in La Jolla, California,

during the 12-month period spanning July 18, 1997 (the release date of the dual chamber ICD) to July 17, 1998. The data obtained included demographic information, indications for dual chamber ICD implantation, and surgical and technical details regarding the ICD insertion. Specifically, surgical details included operative time, fluoroscopy time, lead and/or connectors required, and any unusual surgical challenges encountered. Concurrent controls consisted of all patients at our institution receiving a single chamber ICD during the same time period.

Indications for single and dual chamber ICD were left to the implanting physician but documented. Indications for pacing were categorized into one of three groups: (1) Class I traditional pacemaker indications from the American College of Cardiology/American Heart Association (ACC/AHA) Committee on Pacemaker Implantation, (2) other (or no) indications for pacing, and (3) indications specific to an ICD population such as a history of inappropriate shock therapy for atrial arrhythmias.[6]

Device and Lead Information

The dual chamber ICDs studied were the Ventak atrioventricular (AV) models 1810, 1820, and 1821 (Guidant/CPI, St. Paul, MN, USA). The ICDs are 73–85 cc in volume and 136–158 g in weight (Fig. 1). For generator changes, the shocking and ventricular rate sensing leads were maintained whenever possible. For new implants or those requiring new leads, patients received a transvenous defibrillating lead (Endotak/DSP models 0125, 0094, or 0095, Guidant/CPI) dual coil single lead and an atrial bipolar lead (models 0015, 4269, or 4440). Lead adapters included rate sensing lead extension (model 6984M, Medtronic, Minneapolis, MN, USA) and Y connectors (Guidant/CPI models 6835 and 6836). The single chamber defibrillators included several models from Guidant/CPI or Medtronic.

Implantation Technique

Our technique for the implantation of a single chamber ICD is described elsewhere.[7] Typically, we used a left cephalic vein approach for lead insertion and a left subpectoral anterior location for the device. For generator changes,

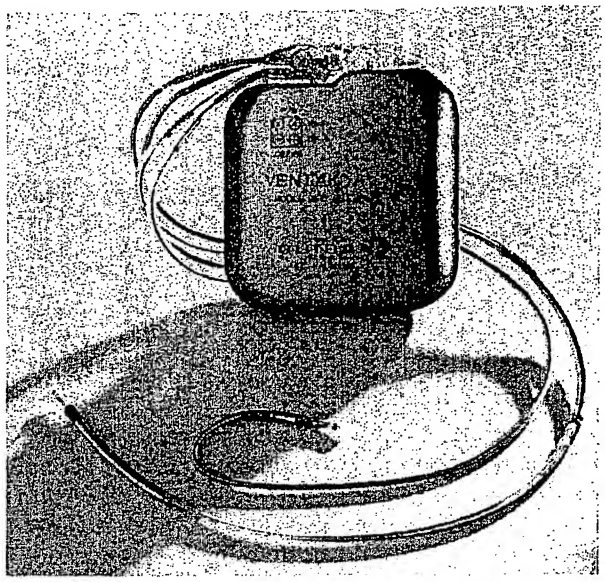

Figure 1. *Photograph of the dual chamber ICD with leads inserted. This version (model 1820, Guidant/CPI, St. Paul, MN, USA) has 4 ports in the header, 1 to accommodate the IS-1 inline bipolar atrial pacing lead and 3 for the ventricular lead including the IS-1 bipolar ventricular pacing/rate-sensing lead and 2 ports for the DF-1 ventricular shocking electrodes.*

many different situations were encountered. In those with a previously separate dual chamber pacemaker and ICD, attempts were made to maintain functioning leads, even if this required lead extension or tunneling. For those receiving a new lead or leads, the left subclavian or cephalic vein was used even if this site had been used for prior leads. If access could not be obtained, the contralateral side was used. If transvenous leads were abandoned, extraction using a counter-traction technique was performed at the discretion of the implanting physician.[8] Procedural times were calculated as "skin to skin," from the first incision or venipuncture to the final suture. Fluoroscopy times were accumulated by the test equipment, representing time only when the x-ray unit was transmitting an image.

Defibrillation Threshold Testing

We performed detailed step-down defibrillation threshold (DFT) testing in all patients using

Table I.

Distribution of Demographic Data

Procedure Type	N	Age	Sex (% Male)	Ejection Fraction (% mean)	NYHA Class (mean)
Single change-out	24	66.7 (± 14.2)	87.5	35.9 (± 0.12)	1.9
Dual upgrade	34	73.8 (± 11.6)	88.2	30.0 (± 0.06)	2.2
New single implant	55	68.7 (± 14.6)	80.0	34.5 (± 0.14)	1.9
New dual implant	61	70.8 (± 13.5)	85.2	31.3 (± 0.11)	2.1
Mean	174	69.1 (± 4.6)	84.5	32.7 (± .04)	2.0

Values are given as mean ± SD. "Single" and "dual" refer to the chamber for implantation; change-out to generator change only; see text for details.

our previously published protocol.[7] This used an initial shock of 11 or 14 J (stored energy) with step-down to failure in 2- to 5-J increments. If a ≥ 9 J safety margin could not be achieved, lead repositioning was first attempted, followed, if necessary, by the insertion of a subcutaneous array lead (Model 0049, Guidant/CPI).[9]

Statistics

All data are expressed as mean value ± 1 SD. The Student's *t*-test used two-tailed groups of unequal variance. Where possible and appropriate, exact statistical methods were used in calculating regression statistics and P values for binary data (StatXact3 for Windows, Cytel Software Corp., Cambridge, MA, USA and Excel 97, Microsoft Corp., Redmond, WA, USA). A probability value < 0.05 was statistically significant.

Results

During the 12-month period, a total of 174 ICDs were inserted at our institution. This included 95 (55%) dual chamber devices and 79 (45%) single chamber. Demographic data is reviewed in Table I. The table is divided into four categories, single (to single) chamber generator changes, dual chamber upgrades (from a single chamber ICD and/or single chamber pacemaker), new single chamber ICD insertions, and new dual chamber ICD implantations. Our population was predominantly male (84.5%), older (69.1 years), with poor left ventricular (LV) function (mean ejection fraction [EF] 32.7%), and with symptomatic congestive heart failure (New York Heart Association [NYHA] Class II). It should be noted that at the initiation of the availability of the dual chamber ICD, we had a waiting list of 12 patients

Table II.

Implant Data

Procedure Type	N	New Leads		Procedure (min)	Fluoroscopy (min)	Implant Location (%)			
		Atria	Ventricle			L. Pect.	R. Pect.	Abd.	Multiple
Single change	24	0	4	29.6 (± 6.2)	0.3 (± 0.2)	8.3	4.2	79.2	8.3
Dual upgrade*	34	28	16	64.9 (± 15.8)	6.3 (± 7.2)	17.6	2.9	8.8	70.7
New single implant	55	0	55	38.9 (± 7.2)	1.5 (± 0.8)	91.0	1.8	7.2	0
New dual implant	61	61	61	57.4 (± 8.9)	4.4 (± 2.2)	93.4	1.6	4.9	0

Values are given as mean with standard deviation in parenthesis. See Table I for abbreviations. L = left; R = right; Pect = pectoral site; Abd = abdominal site; Multiple refers to the need for two or more incision sites.
*The dual chamber upgrades are further characterized in Table III.

who had a pacemaker, ICD, or both and were in need of upgrade. Between the four groups outlined in Table I, there were no statistically significant differences in clinical characteristics.

Implant Data

Table II reviews the implant data using the same patient population breakdown as in Table I. In the single chamber ICD generator change group, four required new ventricular lead insertions, all of whom had prior epicardial systems. One of these had evidence for lead erosion and three had an elevated capture threshold of the epicardial pacing leads. With two of these, the generator was also moved to a left pectoral site, resulting in a classification of surgery at multiple sites in Table II. The new implants, single and dual chamber, were predominantly in the left pectoral locations though patient-specific issues (prior radiation therapy in 1, indwelling dialysis catheter in 1, and preference for abdominal generator in 7) occasionally dictated a variation.

Procedural and fluoroscopy times were longest for dual chamber upgrades as these procedures often required insertion of a new lead in a site where a preexisting lead was present and/or tunneling of preexisting leads to new sites. New dual chamber implants averaged 57.4 ± 8.9 minutes for total procedural time. However, there was an evident learning curve as demonstrated in Figure 2. In the last 30 dual chamber implants, the average implant time had decreased to 45.1 ± 6.1 minutes. The decrease in standard deviation suggests improved consistency of implant time. The negative slope (−0.52) of the regression line in Figure 2 confirms the trend toward shorter procedures with increased experience.

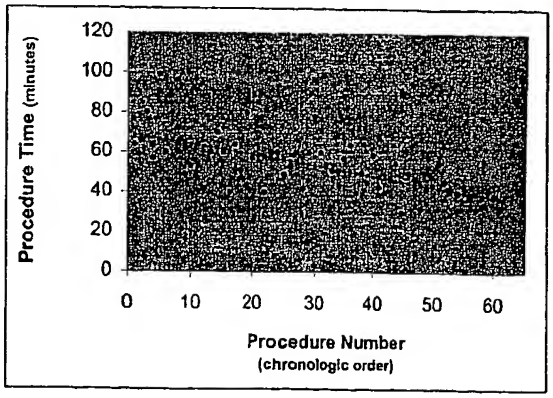

Figure 2. *Plot of the procedural time for the 61 dual chamber implants listed in chronological order during the first year of implantation. The regression line has a negative slope (−0.53, $P < 0.05$) denoting a learning curve where implant time lessens with greater experience, despite experience with similar devices.*

The addition of a second lead (atrial) adds an average of 18.5 minutes to the new implant's duration. Only 2.9 minutes can be attributed to direct fluoroscopy time though this only quantitates the time when the fluoroscope is on;

Table III.

Dual Chamber ICD Upgrade Implant Data

Previous Device Implant	N	Procedure (min)	Fluoroscopy (min)	Implant Location (#)*		
				L. Pect.	R. Pect.	Abd.
Abdominal ICD	20	65.0	7.3	10	1	20
Pectoral ICD	6	52.2	3.5	6	1	0
Pectoral Pacemaker	2	60.0	3.7	2	1	0
Pacemaker and ICD	6	78.9	4.2	6	3	5
Mean	34	64.9 (± 15.8)	6.3 (± 7.2)			

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*Values add up to greater than N as patients may have required multiple sites.

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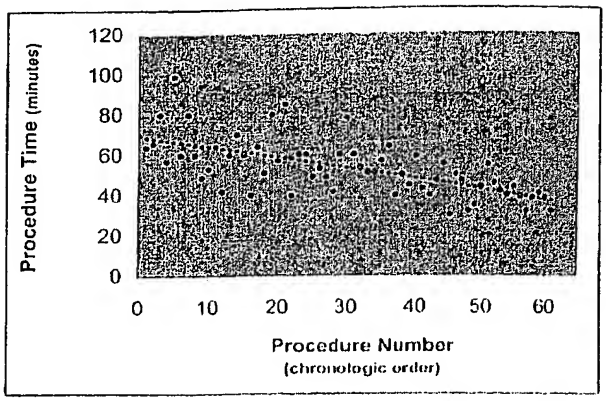

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other procedural time may also be expended to achieve a viewable x-ray image. Thus, it is not possible to accurately determine the reason that the addition of an atrial lead extends the average implant by 48%.

Dual Chamber Upgrades

The dual chamber ICD upgrades comprised an inhomogeneous group that is best understood with further subclassification. Table III summarizes the implant details of these upgrade patients classified by previous device implant and site. The largest upgrade group comprised 20 (59%) patients who had a previous abdominal ICD with epicardial or transvenous leads. Predominantly due to patient preference, half had their generator moved to a left pectoral site since a thoracic incision was needed for a new lead. These patients all received a transvenous ventricular defibrillating lead and the new atrial lead. In patients with a preexisting transvenous lead to an abdominal pocket, we usually maintained the abdominal site by tunneling a new atrial lead. For fear of damage, we did not attempt to tunnel a chronic transvenous lead from the abdomen back to a pectoral location.

At the time of our study, there was only one long (100 cm) atrial pacing lead available for abdominal implant (Model 0015, Guidant/CPI). While any pacing lead can be adapted for abdominal use with the addition of an extension connection, we generally reserved these extensions for chronic leads as the potential for sensing problems is amplified with any modification.

In the dual chamber upgrade subgroup, each patient presented unique challenges. Figure 3 depicts a typical problem. Panel A shows a right-sided dual chamber pacemaker with a right-sided defibrillator lead tunneled to an abdominal generator. Prior to reoperation, two problems were noted: an elevated defibrillation threshold (20 J) and intermittent loss of atrial capture. At reoperation, venous access was not attainable via the right subclavian or right cephalic veins as subclavian occlusion was documented with contrast venography. Therefore, all three leads were extracted and a new dual chamber ICD system inserted via the left cephalic vein. Operative time was 70 minutes and fluoroscopy time 4.5 minutes.

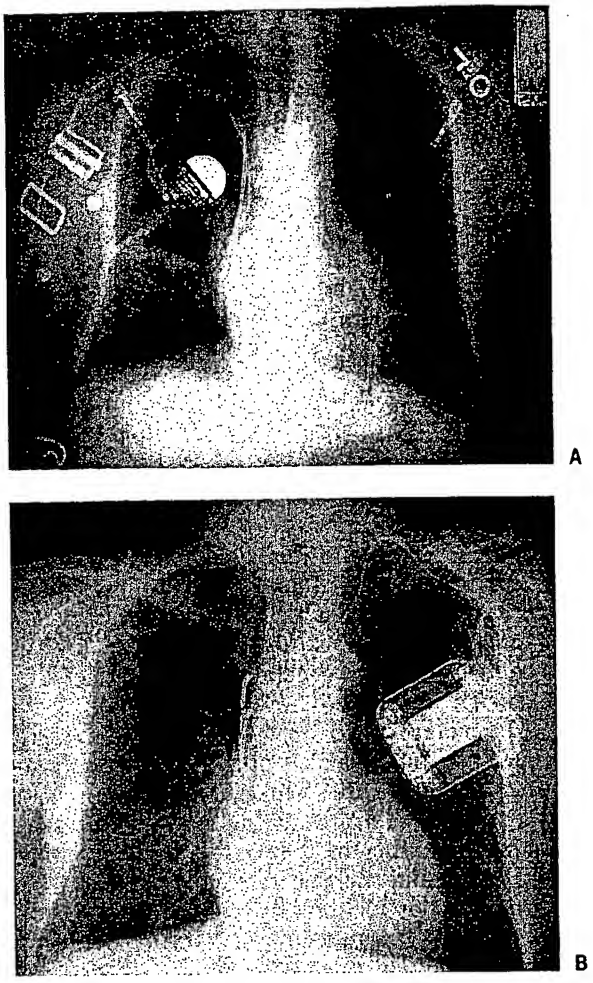

Figure 3. *Chest radiograph of a patient prior to (Panel A) and after (Panel B) dual chamber ICD upgrade. This patient had a preexisting right pectoral dual chamber pacemaker with a right abdominal defibrillator, neither of which could be used for the upgrade. The postimplant radiograph shows the new dual chamber ICD and leads in the left pectoral location after successful extraction of the chronic pacing and defibrillating leads.*

Indications for Pacing

We retrospectively reviewed the indications for pacing in the 95 patients receiving a new dual chamber system or an upgrade to a dual chamber device. These are reviewed in Table IV. These were classified into classic pace-

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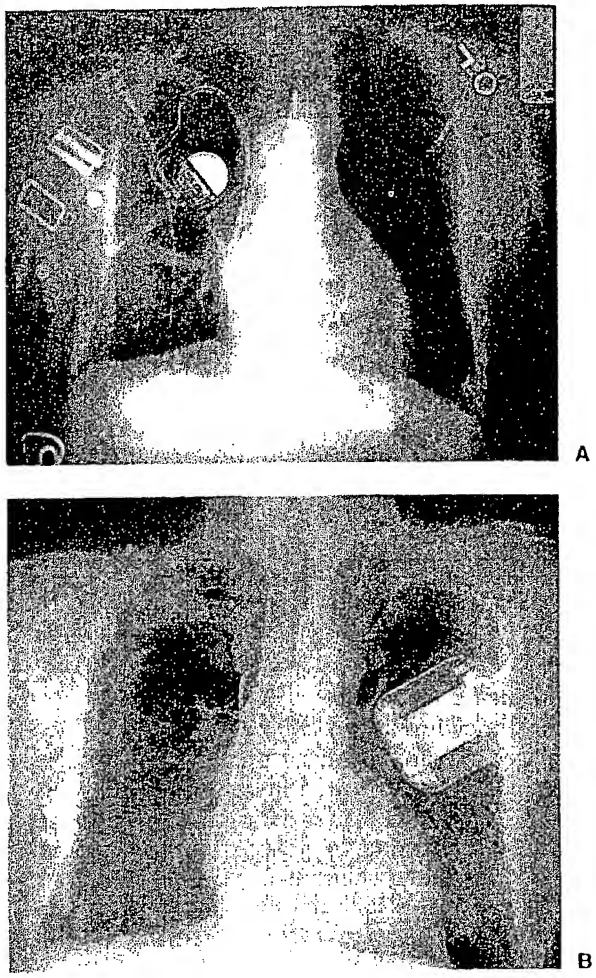

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Table IV.

Dual Chamber ICD Indications

	New Dual	Dual Upgrade	Total
Classic Indications (Type I ACC/AHA)	**32**	**16**	**48**
Sick Sinus Syndrome (tachy-brady)	6	4	9
Symptomatic sinus bradycardia or pauses	9	6	16
Paroxysmal AF with symptoms and slow response	8	4	13
Second-degree AV block or HP block with symptoms	3	0	2
Complete heart block with symptoms	6	2	8
Other Indications	**14**	**1**	**15**
Asymptomatic second- or third-degree AV block	1	0	0
Syncope w/o assoc. AV block but with abnormal EPS	8	0	10
HV interval > 84 ms or pacing induced HP block	6	0	4
Hypertrophic cardiomyopathy	0	1	1
ICD-Specific Indications	**15**	**16**	**31**
Inappropriate shocks for atrial arrhythmia	0	5	7
Severe CHF with bradycardia or conduction disease	15	11	24
Prior Pacemaker Implantation	**0**	**2**	**2**
Pacemaker implanted due to sick sinus syndrome	0	0	0
Pacemaker implanted due to complete heart block	0	2	2
Total of all Indications	**61**	**34**	**95**

AV block = atrioventricular block; CHF = congestive heart failure; HP = His-Purkinje; AF = atrial fibrillation. w/o assoc = without associated.

maker implantation indications (Class I from the ACC/AHA guidelines), ICD specific indications, and others. In the new implants, the largest group (52.5%) had classic indications predominantly due to sinus node dysfunction. In the patients with a previous ICD undergoing upgrade to a dual chamber device, there were an equal number (47.0% each) with classic indications as there were with ICD specific indications, predominantly mild conduction disease (e.g., first-degree AV block) with severe symptoms of congestive heart failure.

Learning Curve

We observed a learning curve regarding both procedural time and fluoroscopy time for these first dual chamber ICD implants, shown in Figure 3 ($r^2 = 0.44$). Each implanter (SLH, DBM) had experience with implantation of over 1,000 ICDs and 1,000 dual chamber pacemakers prior to this study. Nevertheless, there is a definite trend toward a shorter procedural time over the 12-month period (regression line slope -0.53, $P < 0.05$).

Complications

In the 174 implants, the complication rate was low (total 2.8%). There were no observed pneumothoraces, pulmonary emboli, hemorrhages requiring transfusion, lead dislodgements, or deaths. There were two pocket hematomas requiring evacuation (one each in the single and dual chamber groups). We did observe three (8.8%) late infections in the patients requiring dual chamber ICD upgrade compared with no infections in the three other subgroups ($P = 0.08$). There appeared to be no common explanation as the organism was different from all three. All required system removal with reinsertion at a later date. In a prior publication of 200 implants from our center, we observed no infections.[7] This dual chamber upgrade group also had the longest procedure times (64.9 ± 15.8 minutes vs the group average 45.4 ± 11.2 minutes, $P < 0.05$).

Discussion

Our first year with the dual chamber ICD has proven to be educational. Despite suggestions by some that the devices will be used infrequently, we used more dual chamber devices (55%) than single chamber devices for new implants.[4] This parallels, though exceeding, the total experience in the United States to date. The manufacturer of the only approved dual chamber ICD in the United States found a 46% dual chamber device use in the first year, translating to a 24% use for the market as a whole. With anticipation of a second manufacturer's dual chamber device approval, projections are that up to 55% of the 1999 ICD implants in the United States to be dual chamber devices.[10]

The extent of the learning curve surprised us (Fig. 2). Despite substantial previous experience with dual chamber devices and transvenous ICDs, implantation times for the dual chamber ICD improved over the first year of use. This may be attributed to modifications in the technique (e.g., insertion of a guidewire to ease atrial lead insertion when placed adjacent to a ventricular lead in a small cephalic vein), greater familiarity with the programmer software, or other factors. It is not known whether the improvement will extend beyond 12 months, though the curve obviously must flatten as extrapolation crosses the abscissa at 134 patients.

The greatest challenge occurred with procedures to upgrade from a single chamber device to a dual chamber ICD where we encountered many obstacles. Each patient required a unique operative plan so generalization is difficult. However, one major conclusion can be drawn: a simpler result is preferable, even when that requires a more complex operation. For example, we attempted to extract unnecessary leads and insert a new pectoral dual chamber system whenever possible. Of course, we did tunnel a long atrial lead to a chronic abdominal site if there were no other factors encouraging device repositioning. However, we attempted to avoid lead extensions and tunneling of chronically implanted leads to minimize late sensing problems. Thus, a "simpler" result often necessitated a lengthier procedure due to the need to extract leads or move the generator from a chronic abdominal site to a new pectoral location. As a group, dual chamber upgrades were significantly longer (64.9 ± 15.8 minutes) than any other ICD implantation procedure (group average 45.4 ± 11.2, $P < 0.05$). These longer operative times in patients with chronically implanted hardware may have contributed to the trend toward more infections in this group.

Unlike dual chamber pacemakers and single chamber ICDs, there are no published practice guidelines for dual chamber ICD insertion.[6] We and others have published anticipated benefits of dual chamber pacing with an ICD.[4,5] Therefore, our chosen indications for selecting a dual chamber ICD are not surprising (Table IV). Whether it was a new dual chamber device or an upgrade from an existing device, approximately half of the patients had "classic" indications, consistent with the Class I ACC/AHA guidelines for pacing therapy.[6] Unique "ICD specific" indications comprised the second largest category as we often upgraded to a dual chamber device when patients had severe congestive heart failure (CHF) associated with relatively mild conduction disease (e.g., marked first-degree AV block) that did not meet Class I pacemaker indications. As further data surfaces supporting the benefits of pacing in CHF, this category importance may grow, though biventricular pacing leads may be necessary.[11]

The dual chamber ICD has become a common device at our institution, and indications have extended beyond published indications for dual chamber pacing. For new insertions, the addition of a second lead was time-consuming as it did add > 18 minutes to the total procedure time compared to new single chamber ICD insertions. A learning curve was demonstrated suggesting this delay may diminish with further experience. The greatest procedural challenge concerned dual chamber ICD upgrades that required individual procedural plans and flexibility when intraoperative obstacles were encountered. Nevertheless, a successful outcome was achieved in 100% of upgrades attempted, although postoperative infection is a concern. As greater experience is achieved and benefits demonstrated, it is predicted that dual chamber implants will become increasingly common. It is likely to that they will exceed 50% of new implants at most institutions in the next year.

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